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NATIONAL INSTITUTES OF HEALTH

MEETING

From Data to Discoveries:

Creating a Research Program for All of Us

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Monday, May 6 , 2019

10:00 a.m.

National Institutes of Health

Clinical Center

Building 10

Masur Auditorium

10 center Drive

Bethesda, MD 20852

REPORTED BY: KeVon Congo, Notary Public

JOB No.: 3287408

SPEAKER LIST

- 1
- 2 Stephanie DeVaney, Ph.D, Master of Ceremonies
- 3 All of Us Research Program, National Institutes of
- 4 Health
- 5 Francis S. Collins, M.D., Ph.D, Director,
- 6 National Institutes of Health
- 7 Ana Pavon, All of Us Research Program Participant
- 8 Ambassador
- 9 Robert A. Winn, M.D. Associate Vice Chancellor for
- 10 Community Based Practice
- 11 Deven McGraw, J.D., General Counsel and Chief
- 12 Regulatory Officer Citizen
- 13 Elizabeth Coh, Ph.D., N.P., R.N., Rudin Professor of
- 14 Community Health Hunter-Bellevue School of Nursing
- 15 David Glazer, Engineering Director, Verily
- 16 Nora D. Volkow, M.D., Director, National Institute on
- 17 Drug Abuse, National Institutes of Health
- 18 Gary, Gibbons, M.D.
- 19 Eric Dishman, Director, All of Us Research Program
- 20 Vick
- 21 Unidentified Speaker from Audience
- 22 Cliff Andrews

1 MS. DEVANEY: Good morning. Good morning,
2 welcome, my name is Stephanie Devaney, the Deputy
3 Director of the All of Us Research Program, and I'm
4 thrilled to see you all here today as we celebrate one
5 year since we, at the All of Us Research Program
6 launched nationally.

7 Welcome to all of you here in the room and
8 everyone who is watching online. Thank you. Today is
9 an important opportunity for us to reflect on what
10 we've achieved, and most importantly to acknowledge
11 the contributions of more than 230,000 participants
12 who have already begun the process of joining our
13 program.

14 Our participants currently hail from 50
15 states, and 80% are from communities and groups that
16 have been historically under-represented in biomedical
17 research.

18 It is this fact that makes us most proud
19 today. Our community of dedicated researchers,
20 participant partners, consortium members and advocates
21 have come together to build something truly awesome.

22 At the same time, we recognize that this

1 program is still in its infancy. We have so much work
2 yet to do from motivating one million or more
3 individuals to become our partners, and generously
4 share information and data about themselves, to
5 building out key components like our genomics
6 pipeline, including the return of genetic information
7 to those participants who want to receive it, opening
8 up access to researchers through our research hub.

9 We are furiously working to deliver what
10 matters most to you as researchers, clinicians,
11 participants, and our advocates. Today's program is
12 designed to share with you the scientific
13 possibilities that exist with a cohort and dataset of
14 this scope and size.

15 You'll hear from our own Francis Collins,
16 Eric Dishman, Nora Volkow and Gary Gibbons. We're
17 also joined by leaders from within our consortium,
18 coming to us from the University of Illinois at
19 Chicago, citizens, the Hunter-Bellevue School of
20 Nursing and Verily.

21 Everyone on stage today brings with them a
22 diverse perspective informed by both our professional

1 achievements and our personal passion. But what
2 brings us all together here today is our shared desire
3 to bring fruition to precision medicine.

4 It is our belief that with more precise and
5 diverse data, we can enable research that can help
6 build a future where health disparities are reduced
7 and entire communities who for so long have been
8 under-represented, can be empowered.

9 And with that, I will pass the microphone
10 over to a man who truly needs no introduction, our NIH
11 Director, Doctor Francis Collins. Francis saw the
12 value of precision medicine more than 15 years ago
13 when he was spearheading the completion of the human
14 genome project.

15 And today, his talk, the research promise of
16 All of Us, will delve deeper into the scientific
17 impacts of the All of Us research program. Thank you,
18 Francis?

19 MR. COLLINS: Thank you Stephanie and good
20 morning to all of you. I am delighted to be here, to
21 celebrate this one-year anniversary of the launch of
22 this flagship enterprise. Whether you're joining us

1 here on the NIH Campus, here in the Masur Auditorium,
2 or by video, or watching the livestream all around the
3 country through our Facebook Live connection. I think
4 we're all eager to hear what's happened to all of us
5 in this one-year since this nationwide launch.

6 I think many of you are already familiar with
7 All of Us and its bold enterprise aiming to enroll one
8 million Americans from all walks of life, from across
9 the United States, asking them to volunteer their data
10 to help find answers about any number of health
11 conditions.

12 The goal is to help speed up medical research
13 and usher us into this new era of precision medicine
14 where prevention and treatment is no longer one size
15 fits all but tailored to the individual.

16 When I look at where we are today, it is hard
17 to believe that it was just a year ago that I stood
18 with Dara Richardson-Heron in the Abassinian Baptist
19 Church in Harlem, New York City for the launch -- one
20 of the seven locations in the country where we were
21 launching on that remarkable day.

22 I hoped then that many would share this

1 vision and help us achieve this common goal of
2 building a research resource that would make possible
3 the next great discoveries in health and medicine.
4 And boy, have you answered that call. It is
5 gratifying indeed.

6 More than 230,000 people across this country
7 have started the process of joining the All of Us
8 research program and more than 142,000 have completed
9 the full protocol. That includes answering surveys,
10 agreeing to share electronic health records, giving
11 physical measurements, donating bio samples and even
12 linking their Fitbit data.

13 That's a lot of valuable data for researchers
14 to explore and make those next great discoveries for
15 health. And not only have we built a large research
16 resource, but as you just heard from Stephanie, we've
17 done it with partners from diverse communities.

18 Almost 80% of the participants so far are from
19 communities that typically have been under-represented
20 in research and 50% are racial and ethnic minorities.

21 Too often such diverse communities have been
22 left out of research and therefore left behind when

1 cures are discovered. So, all of us aim to make a
2 profound commitment to understand and chip away at
3 those vexing health disparities, that is a major part
4 of our goal.

5 So, in just one year, and even though only
6 part-way to the enrollment goal, All of Us has managed
7 to become one of the largest, most diverse research
8 resources in history.

9 I want to offer my thanks to the
10 participants, the community partners, and the
11 passionate research teams around the country who have
12 made this possible.

13 But I want to focus today on this one-year
14 anniversary on another important question, what is
15 next? Well, now that we're gathering the data, what
16 kind of research breakthroughs will all of us enable?

17 And how can the research community, both
18 traditional researchers and citizens scientists help
19 us in this next step of the All of Us journey?

20 Well before I pull out the crystal ball about
21 the future of All of Us, maybe take a moment to look
22 back in time to see if there's a precedent here.

1 Let's think back to 1948, in the little town of
2 Framingham, Massachusetts. There more than 5,000
3 people volunteered for a study to find answers about
4 the mysterious growing epidemic of heart disease.

5 Every two years for decades, they had a
6 physical exam, gave blood and urine samples, and
7 answered questions about their health. Over time,
8 their children and grandchildren joined too,
9 ultimately, about 25,000 participants.

10 Because of them, we now know the big risk
11 factors for cardiovascular disease and have saved
12 millions of lives through new prevention strategies,
13 development of drugs, procedures and education.

14 So, in some ways, All of Us is a bit like
15 Framingham, but 40 times bigger, covering all health
16 conditions, consisting of a much more diverse cohort,
17 and using technologies never dreamed of in 1948.

18 Now, if a study of just 5,000 people could
19 contribute to a 67% decrease in deaths from heart
20 disease in the past several decades -- that's what's
21 happened, I think it's safe to say that the potential
22 for All of Us is almost boundless.

1 So, what kind of advances might be catalyzed
2 by this unprecedented program? For more than a year
3 ago, the NIH convened a workshop on research
4 priorities which helped articulate some specific
5 applications, hundreds of them in fact, use cases we
6 call them.

7 One key area discussed was diabetes.
8 According to the CDC, more than 30 million Americans,
9 or almost 10% of our population have type 2 diabetes
10 and another 84 million have pre-diabetes and are
11 likely to go on to full-blown diabetes in the future
12 if nothing happens.

13 With the All of Us dataset of one million
14 participants -- well, do the math here. We may expect
15 about 90,000 of those participants to have diabetes,
16 and as many as 300,000 to have evidence of pre-
17 diabetes.

18 Since this program aims to follow
19 participants for at least a decade, if not longer,
20 some people may develop diabetes while enrolled, and
21 others may be able to avoid the condition due to early
22 diagnosis and effective treatment.

1 So, with access to the electronic health
2 records, researchers may be able to explore early
3 signs and symptoms and compare the effectiveness of
4 various prevention strategies.

5 Since All of Us will also pull in
6 environmental data using linkages to national
7 databases, researchers can look into the environmental
8 risk factors for diabetes.

9 And with the genomic data available, a better
10 understanding of the genomic factors that confer risk
11 should also emerge. I'm willing to predict that we
12 will be able to demonstrate that what we currently
13 call type 2 diabetes, will actually turn out to be
14 made up of several sub-types, each with different
15 factors for vulnerability and resilience, and with
16 different responses to treatment.

17 Because All of Us isn't just about building a
18 dataset, but also about building a community of
19 participants who are empowered and exciting to support
20 medical research, interested researchers will have the
21 opportunity to invite diabetic or pre-diabetic
22 participants to join follow-up studies.

1 This could give clinical researchers an
2 opportunity to test health intervention to see if they
3 may be effective in early detection and treatment of
4 pre-diabetes, or in trying new interventions for those
5 diagnosed with the disease, such things as the
6 artificial pancreas.

7 Another promising area that the workshop
8 identified was Alzheimer's disease, a condition that
9 all of us can agree that's desperately in need of new
10 insight about prevention and treatment.

11 Genetic sequencing and family health history
12 can help us identify All of Us participants who may be
13 predisposed to Alzheimer's or other forms of dementia
14 by following their lifestyle choices through such data
15 items as surveys, wearable devices, recording exercise
16 and sleep, diet diaries, and potentially even
17 microbiome samples, we will be able to see if any of
18 these variables can influence an individual's risk for
19 developing a condition.

20 We might even use smart phone-based
21 assessments, of voice and speech, to see if they can
22 help us predict the onset of Alzheimer's or response

1 to treatment. And as with diabetes, when promising
2 new treatments for high-risk individuals emerge, All
3 of Us participants will be in an excellent position to
4 enroll quickly -- to enroll quickly and efficiently.
5 These are just the possibilities for two conditions.

6 All of Us can empower studies in many areas -
7 - cancer, infection, mental health, vision or hearing
8 loss, kidney disease, pain, and so much more. You'll
9 hear more specifics from Nora Volkow and Gary Gibbons
10 about examples of research in their domains that they
11 envision All of Us can empower.

12 And I invite all of you to imagine the ways
13 in which this resource can plead up your own research
14 studies. So, now that I've gotten you thinking about
15 the possibilities of the dataset, you may be wondering
16 how you can access the data.

17 You'll hear more from Eric Dishman about how
18 you can get a glimpse of this type of aggregated data
19 that's been collected so far, starting today. But
20 researchers will especially want to watch for the
21 launch of the Researcher Workbench containing more
22 data and the first set of researcher tools which will

1 launch this winter.

2 The precise timeline is dependent on the
3 outcomes of our usability and security testing. Now
4 when that Research Workbench is made available it will
5 include data for upwards of 200,000 participants. It
6 will include survey results, measurements, and
7 electronic health record data.

8 I anticipate these hundreds of thousands of
9 datapoints just by themselves, will be very useful for
10 researchers and will lead to many interesting studies.
11 More data, from new participants who join and from
12 additional data collection activities, will be added,
13 greatly increasing both the quantity and quality and
14 diversity of the data.

15 I know that many of you, like me, are also
16 eager to access additional data types such as genomics
17 or wearables data. The All of Us team is hard at work
18 on plans to add those data to the dataset and are
19 targeting a launch for their inclusion in 2020.

20 The team is also busy building out its
21 scientific roadmap and planning for even more data
22 types, additional laboratory assays, new surveys or

1 measurements, and linkages to external datasets. Not
2 only will All of Us continually expand the dataset,
3 they will also be increasing and improving the
4 analytic tools that will be available to you through
5 the Researcher Workbench.

6 The All of Us team will vouch for the fact
7 that I'm always pressuring them to go faster. They're
8 laughing about that, but I want to point out that in
9 fact All of Us is operating under a very bold
10 timetable.

11 Most research programs of this scale don't
12 release data until several years after they've
13 completed enrollment of the last participant. Our
14 attitude here is very different. The team will do
15 everything we can to meet these bold targets.

16 But we have another even higher
17 responsibility to consider. Our highest commitment
18 must be that we make sure that data is always secure,
19 and that we are protecting the privacy of our
20 participants. Therefore, everything we do will be
21 subject to rigorous security and privacy testing.

22 So, to conclude my part of this morning's

1 special event, All of Us is on a journey where the
2 dataset will continue to grow, and the tools will
3 become more refined. We invite you to join us early
4 as participants and as researchers, not only so you
5 can begin using the data for discoveries, but also so
6 you could get input and feedback and help us design
7 the best research platform and dataset to help us
8 accelerate research.

9 Thing of all of us as a one-year old, just
10 having learned to walk, maybe babbling a little bit,
11 I'm sure it said something really important about
12 precision medicine and All of Us nurturing this
13 enterprise, trying to help this little one grow up to
14 become an incredible contributor to the future of
15 health in our nation and across the world.

16 So, I'm incredibly excited about the
17 potential of All of Us, and I look forward to seeing
18 how much this program can profoundly benefit the
19 future of health.

20 You know it wasn't in my script, I think we
21 probably should sing Happy Birthday to All of Us. So,
22 all together now in the key of G, (sings Happy

1 Birthday). Back to you Steph.

2 MS. DEVANEY: Thank you Francis, we will have
3 cake later, not purchased with appropriated funds to
4 be sure. Thank you Francis, your vision has been the
5 guiding force behind this program for many years since
6 it was really just an idea in someone's head and
7 before we fully formed and brought on the hundreds of
8 partners and thousands of people working with us on
9 this program across the country.

10 So, now I'm going to move us into our
11 lightning talks round and this truly will be lighting
12 talks. We have seven compelling talks from both
13 leaders within our program and leaders from here at
14 the National Institute of Health.

15 We're going to -- I'm going to introduce our
16 first speaker and I'm very honored to introduce her.
17 Ana Pavón is one of our participant ambassadors
18 meaning that she has not only joined the program but
19 has truly become a partner in the program helping to
20 guide and shape the decisions that we make about All
21 of Us.

22 Ana is a champion for rural immigrant

1 community in South Carolina and for her son who has
2 experienced an emotional and difficult trial and error
3 medical journey. I welcome Ana to the stage. Please
4 help me to share her story.

5 MS. PAVÓN: Good morning, I'm Ana Pavón, one
6 of the participant ambassadors for the All of Us
7 research program. I'm excited to be here today to
8 share my story with you, so you can see why I'm part
9 of All of Us.

10 My family immigrated to Los Angeles when I
11 was a year old. My mother came from a small village
12 in Vera Cruz, Mexico. She had never been exposed to
13 even the most basic things to the point that she
14 didn't even know what a toaster was.

15 This lack of exposure translated to how we
16 received care. Our illness were treated at home. I
17 never say a pediatrician growing up. One day I needed
18 dental care. My mom met a friend at church who
19 offered dental services in his home, so that's where I
20 went.

21 In 2001 I moved to South Carolina and later
22 began working at Cooperative Health, a community

1 health center. This was my first real exposure to the
2 healthcare system. The place I worked at served a
3 rural community that included many immigrant farm
4 workers. Because I was bilingual, I was given many
5 responsibilities, often serving as an interpreter and
6 a patient liaison.

7 One day, an adult man came in for his first
8 dental cleaning ever. He had never before seen a
9 dental instrument and perceived them to be torture
10 devices. I helped ease his anxieties by asking him --
11 by talking him through the process.

12 He left the place that day knowing more about
13 dental care, and I knew it would help his children
14 too, as he now understood the importance of beginning
15 early.

16 I was passionate about my work because I saw
17 myself in these workers. I let them know about our
18 programs and I tried to help the staff understand the
19 unique needs of the community.

20 While I was doing this work for our
21 community, I was struggling at home watching my son
22 develop symptoms of a condition I knew nothing about.

1 In 2011 my son was 5 years old when he suddenly
2 started walking differently, awkwardly. He was
3 jerking around, and he described being itchy.

4 I took him to the doctor, the first dozen of
5 appointments and they told me he was fine, but I knew
6 he wasn't. So, I started to take him to Urgent Care
7 where they gave him medications. The jerking stopped,
8 but he developed a vocal tic and would sometimes
9 scream randomly. This was all very new to me and very
10 scary.

11 I kept taking him to the doctor who thought
12 it was allergies and prescribed some allergy drugs.
13 They didn't help and we wanted more answers. So, like
14 many people, I started Googling and I came across
15 Turrets Syndrome -- my son's symptoms being somewhat
16 different from what I read about, so I didn't think
17 more about it.

18 Eventually, the doctor referred my son to
19 psychiatric care. It didn't feel right, but I took my
20 son and they gave him a new medication with some
21 pretty bad side effects. My son's condition kept
22 worsening, he now had a hand and shoulder tic and also

1 started cursing and blurring out derogatory words.

2 At one point, the side effects from the meds
3 made him so depressed that I thought maybe he'd be
4 better off with the tics. It took a chance encounter
5 for my son to be diagnosed with Turrets. His medical
6 condition -- his medical journey has been one of trial
7 and error where we've lost precious time and he's
8 faced horrible side effects.

9 I wonder if precision medicine can one day
10 help lessen these burdens. My son experiences
11 motivated me to get involved with All of Us. I hope
12 one day other parents will have a much easier
13 experience, and I know to do this we must be included
14 in the research.

15 Our population is different. Our health
16 needs are different. We need to participate. The
17 program wants the variety, a diverse selection of
18 people of communities. They want to have a diverse
19 collection of samples -- that to me, matters.

20 From my work with Cooperative Health, I know
21 it won't be easy for some populations to be included.
22 That's another reason I'm working with All of Us, so I

1 can help the program understand the need, culture and
2 also the many friends of my community.

3 We're now at a time where we matter. This is
4 why I believe the future of research is this. Thank
5 you.

6 MR. WINN: Good morning everyone, and for
7 those of you who know me, I will keep this in four
8 minutes. This is a talk about why being represented
9 matters and why actually this was a driving force for
10 me being part of the All of Us program.

11 And in fact, I think I'd like to start off
12 really what the promise of science has been. I've
13 lived through an entire generation where we had
14 classes about genetics, but never thought we'd
15 actually look at the entire genome.

16 It's been wonderful to think about all the
17 things I've been able to do in my lifetime in the
18 context of seeing lung cancer patients, which as a
19 medical student I would have to sort of say, well,
20 there's not much we can do for you. Now, I'm being
21 able to offer immunotherapy, molecular-targeted
22 therapy.

1 I've seen it in my lifetime. We have gadgets
2 like the one you see on this screen where you can take
3 your cell phone, and not only get EKG's, but you could
4 actually diagnose your own kidney stone, and who knows
5 what other things we'll be able to do.

6 It's been great to sort of see that we're
7 working in science in a way in which we can get down
8 to the single cell and I don't know what that is, but
9 that must be the magic fairy sort of thing. This is
10 great.

11 We're down now to the single cell. We're
12 talking about systems files. We're talking about
13 things that we're pushing the envelope that I never
14 thought would be possible when I was a medical
15 student.

16 We're talking about big data that gets bigger
17 every day. The interesting thing about this program
18 though, and why I like it and why representation
19 matters, is because what I've learned from Eric
20 Dishman and what I've learned from Doctor Richardson
21 Erin, is that all data matters, both big and small.

22 And that in our rush to get big data,

1 hopefully we don't make communities invisible. One
2 example of this is if I were just to look at like
3 expectancy in Chicago, I would sort of say, well life
4 expectancy over the United States 79, great, in
5 Illinois roughly 79, good.

6 In Chicago it's roughly 79, except for when I
7 take a more granulated precise look. What I love
8 about really All of Us and the precision medicine sort
9 of program and the approach is that we want to be able
10 to see things that we weren't able to.

11 In this context, you see on your right, you
12 know, something called the loop which is where Oprah
13 Winfrey would tend to hang out. The life expectancy
14 there is 85 and literally that's about 3 miles away
15 from where my cancer center is.

16 By the way, if I take -- go to your left
17 which is east/west, we would go into an area called
18 West Garfield Park. Now West Garfield Park is again
19 about 3 miles away from Kansas Center, but has a
20 different life expectancy -- it's 69. And to be
21 honest with you, for record keeping, just for total
22 transparency's sake, it's actually 68.45, but you

1 know, being in kindergarten and other things, I've
2 learned how to you know, round it up to 69 because I
3 just couldn't take 68, but that's today.

4 So, the promise really of this program gets
5 beyond just the bigness of the data and gets to the
6 functionality of the data and the impact it will have
7 on these communities by seeing them.

8 So, to this, someone say yeah, but how do you
9 get those who are under-represented into biomedical
10 research sort of involved because this is tough
11 business? Right, we know about Tuskegee and the 1932
12 United States Public Health sort of service, sort of
13 experiments that went on that actually thought at the
14 time that syphilis -- African Americans would be a
15 great sort of, control group since syphilis didn't
16 happen.

17 Now the reality about this program is there
18 are lots of examples that you could go back in time,
19 but the one example I want to actually put up there
20 now is this -- when I actually go to the barber shop,
21 when I go to the churches, people are also wondering
22 about what's happening now -- the disparities that are

1 happening now.

2 And how do you get people involved? Well the
3 first thing of getting people involved that I thought
4 was a brilliant move of this program in particular,
5 was to not deny that the past had happened. To say,
6 yes, it did but guess what? We're moving forward.
7 And the reality is you're not going to trust me by
8 just the words I say, but by the behaviors we do every
9 day within the program.

10 I'll give you one quick example. We had a
11 group of 250 African American men on the south side of
12 Chicago who actually volunteered to sort of say not
13 only will we do this, but when we will get our
14 results.

15 It seems like the ancestry part is actually
16 kind of interesting. But more importantly, these same
17 men wanted to know with the town hall that we had with
18 them, when we get these results, I may not be helped,
19 but how is this going to help others? That is a
20 recurring team.

21 So, this myth that minorities will not
22 participate is not so much -- it's not true, it's how

1 we package, how we interact, how we show up, how we
2 gain trust is by showing up, being honest and being
3 consistent. And this program has allowed us,
4 particularly those people who believe that community
5 matters up there.

6 Now, I've come down to my last -- all I'm
7 going to say at this point is I'm going to tell you
8 that I understand that there are a lot of -- a million
9 reasons why this program might not happen, but I'm
10 going to plead to you that it has to. This program
11 ultimately hopefully will bring out the best in us,
12 because when history looks at us, what I'm hoping
13 someone will say is that we may not have gotten
14 everything right in the beginning but we kept it on
15 the tracks and we kept it moving for the future.

16 The reality is this program matters because
17 it's getting people in areas that have never been
18 engaged, engaged in a way and giving them hope that
19 this will help not only them, but help their
20 communities and help their kids. To me, this is more
21 than just science, it really is about the health of
22 the nation and moving it forward by what I love most

1 which is through science. So, with that I want to say
2 thank you very much and I did okay, I think.

3 MS. MCGRAW: Those are tough acts to follow.
4 Good morning. It is really an honor for me to be
5 here, so pleased. I would come all the way from
6 California to be able to be in this building and
7 support this program.

8 Our infrastructure for conducting human
9 subject research is ultimately dedicated to improving
10 the health and well-being for all individuals. I've
11 always thought that researchers are really dedicated
12 to the noble cause of helping people, really through
13 their contributions to advancing medical science, and
14 to learning about what interventions or treatments
15 work best in which population. That helps people.

16 Our research community has for a very long
17 time, really viewed individuals as research subjects,
18 but still also respected their interests and honored
19 their important contributions by asking for their
20 consent first, and through ethical review.

21 But the All of Us research program is forging
22 a different path -- a path where individuals from

1 populations who are often missing from research
2 datasets and who often have deep misgivings about
3 participating in research are actively sought for
4 their contributions.

5 Where individuals are asked to donate their
6 specimens and their data for research purposes, and
7 where individuals have an opportunity to receive some
8 of this data back if they want, where the individuals
9 are participants and not just data subjects.

10 The idea that individuals can and should be
11 able to get their healthcare information and be able
12 to use it and share it as they see fit is not,
13 actually, it's not a new concept. It's an under-
14 utilized concept, but it's not a new concept.

15 Since 2000, the HIPAA privacy law -- I'm
16 continuing to move forward, since 2000, really this is
17 almost two decades now, individuals have had the right
18 under the HIPAA privacy rule to a complete copy of
19 their health information. Again, to use it and share
20 it as they see fit.

21 And I know a little bit about this law
22 because I wrote extensive guidance on it when I was

1 the Deputy Director for HIPAA at the HHS Office for
2 Civil Rights. HIPAA may have been one of the first
3 laws to do this, but new privacy laws, such as the
4 Global Data Protection Regulation in Europe and
5 California's new Consumer Privacy Law, really doubled
6 down on this idea and gives individuals even broader
7 rights to their information in lots of different
8 contexts.

9 Some of you may be asking why is this right
10 to data access part of a privacy law? What do those
11 things have to do with one another? Well, in some
12 respects actually providing individuals with the right
13 to the same information that everyone else has about
14 them is in some ways justification for enabling those
15 entities to collect the data, to be able to themselves
16 engage in broad usage of it, both identified and in
17 de-identified form, including for research.

18 In the medical context, people tell me all
19 the time and I don't think that it's legally right,
20 but still rhetorically has a huge amount of power
21 which is that people frequently consider the data and
22 medical records to really belong to the patient.

1 And I think most importantly, giving
2 individuals the power of their data, it really enables
3 them to take more control of their health and to seek
4 better care for themselves, but also for others. As
5 an individual, when you have your data, you're
6 empowered to seek the care that you need.

7 If you're sick, you can share your data, just
8 to try to help you find a clinical trial and you can
9 donate your data so that the next person who is
10 diagnosed with the illness that you have may have a
11 better chance of surviving or a better chance at a
12 higher quality of life.

13 Most healthcare for individuals happens
14 outside of the clinical office and so enabling
15 individuals to push their clinical data to researches
16 and then supplement that information with data about
17 their daily lives can really enhance research datasets
18 and expand what we can study and learn.

19 Oh, and by the way, individuals can also see
20 this data and see maybe whether it's inaccurate or
21 not, like here are the medications I'm actually taking
22 versus the ones that were prescribed to me, but that

1 I'm not taking because the side effects are really
2 difficult for me to tolerate, or the drug is actually
3 too expensive.

4 Here in the U.S., if not actually globally,
5 we are at a real inflection point around the
6 collection of personal data and the trust in those who
7 are collecting it.

8 And part of building that trust means
9 treating people as collaborators in caring and
10 research and not just as subjects. The All of Us
11 research program is showing us that there is another
12 way.

13 The program is really way out in front of
14 change that is coming. And I'm talking about change
15 that will likely be as a result of some new laws, but
16 also the inevitable cultural revolution that the All
17 of Us research program is out in front of, doing the
18 right thing before you're forced to do the right thing
19 will always put you on the right side of history,
20 thank you.

21 MS. COHN: So, good morning, oh that's great.
22 I'm Elizabeth Cohn. I want to talk with you guys

1 today about some opportunities that this program
2 affords us like no other I have seen in two decades of
3 research with communities and that is the opportunity
4 to think more critically and study more robustly the
5 science of engagement.

6 So, as Doctor Winn pointed out, this takes
7 place in the context of egregious acts under the name
8 of research that have taken place in the past. And
9 one opportunity that I saw with this program was to
10 start to think about the ways that we could repair
11 some of the trust that has been lost.

12 So, some of those include thinking about
13 engagement models and methods. Some simple ones, like
14 the top one, this is a Metro map, so in homage to
15 being here in D.C., this is an engagement awareness
16 education and engagement map that talks about how we
17 can restore trust in communities.

18 So, with a hat tip to Ronnie Tepp at HBM, we
19 can talk about starting way at the beginning, raising
20 awareness, educating people about the purpose of
21 clinical research, establishing ourselves as credible
22 and trustworthy partners, creating a relationship,

1 supporting it and then asking for participation.

2 So, being in and remaining in communities in
3 authentic ways. We can also think about a more
4 complex model and the bottom one is from Corrine
5 Watson, Consuela Wilkins, myself and Usha Menon. When
6 we tried to really take apart what's inside that type
7 of change, so how do we think about and measure
8 context, trust and mistrust, community readiness and
9 outreach and fairness and equity?

10 What are the dynamics that are taking place
11 and how can we influence those? And then what goes
12 into actual engagement, thinking about the integration
13 of cultural knowledge, appropriate research design and
14 community involvement from the ground up?

15 And then we really wanted to think about and
16 develop a set of outcome measures that would point the
17 way towards better, more robust and long-term
18 community involvement.

19 So, what are some of the opportunities then
20 to study trust, to study engagement, to study
21 partnerships? How do we do that? What's the science
22 behind the engagement? What you see down here are

1 pictures from a recent workshop that we did at
2 Columbia University where we brought in 20 community-
3 based organizations and partners of the research All
4 of Us program, and sat down with them through an
5 amazing kind of pilot study funded out of Dara
6 Richardson-Heron's initiative.

7 To think about what are some ways if
8 community organizations are doing education and
9 outreach, and a place like the New York City Precision
10 Medicine Consortium is doing enrollment, recruitment
11 and retention, what do those bridges look like?

12 What do those relationships look like and how
13 can we -- what are the best ways for us to do them?
14 We listened a lot, we learned a lot, and I have to say
15 in that afternoon we laughed a lot.

16 So, there are some things that we knew, like
17 make the outcome of the research meaningful for the
18 community, and there are some things that we didn't
19 know, and we had a lot of time learning them and a
20 great time.

21 So, I just want to end with a couple of
22 lessons learned. I've been with the program almost 4

1 years now, it could be a little bit longer and so, I
2 want to say that over time I've learned that community
3 -- they've often said that community engagement is
4 messy. I don't think so. I think it's just really
5 complex.

6 I had the opportunity to sit in communities
7 and talk to them about civil rights, about civic
8 discourse, about things that have happened in the past
9 and about our collective hope for the future.

10 I think that we've confronted issues of
11 trust, of institutional and structural racism, of
12 people's relationships with their providers. We've
13 offered and received cultural humility, and we thought
14 about having a presence over time in the communities
15 in which we want to work.

16 And that's been ongoing for decades. We have
17 the opportunity in this initiative, unlike any other,
18 to study resilience over disparities and I really
19 encourage people to think about how we can do that in
20 a meaningful way. And done right, it can lead to
21 empowerment and action in community health, which is
22 what we want.

1 I'm not going to go through the column on the
2 right, but I just want to say that within All of Us
3 initiatives now and going forward, we can study things
4 like distributive justice, empowering community
5 advisory boards, capacity building for health in
6 communities that are under-served and under-resourced.

7 We can study trust, and if we wanted to, we
8 could study the cost and effectiveness of some
9 recruitment of minorities, but that to me, is just
10 another kind of way to -- another lens in which to
11 view some of the work that we can do, thank you.

12 MR. GLAZER: Hello, I'm David Glazer and I
13 have the privilege of talking about the technology
14 that we are building to advance the goals and missions
15 that we just have heard about.

16 When we build the technology platform, the
17 first question is always what are we trying to
18 accomplish? Who are we building it for, what problems
19 are we trying to solve? And the first people that we
20 listened to as we were designing and shaping the
21 technology platform, were of course, the participants.

22 And many of us on the technology team are

1 participants. So, when we say we need and we want,
2 we're talking both in the larger sense and about our
3 own personal desires. And the first and loudest
4 request was make sure that the data I'm donating is
5 stored in a reliable way.

6 Make sure that this is actually -- you're
7 honoring my donation. Second, and at least as
8 important, probably more important, is do something
9 with it. Make a difference, right? I'm donating this
10 data. We heard from Ana, we've heard from many
11 people, I'm donating this because I want to make a
12 better future.

13 Make sure that the data that we are donating
14 is widely available for appropriate us to reach the
15 biomedical goals that we think are possible and that
16 Doctor Collins laid out at the beginning.

17 And then third, and all of these are
18 critical, third is keep our data safe from
19 inappropriate use. So, these were the goals --
20 reliable, available and safe. Now, from a researcher
21 perspective, similarly, there were a set of goals that
22 we heard regularly.

1 The first goal was -- give me a powerful
2 platform. Give me an environment that let's me use
3 the right tools and gives me rich data and let's me
4 use those tools to find all the possible meaning in
5 that data.

6 And that's a platform that was going to grow
7 over time. We know that on day one it will have a set
8 of tools and then we will hear and iterate and add
9 more.

10 The second thing that we saw an opportunity
11 to in this era, is say let's make sure that the
12 researcher platform is collaborative, that it enables
13 to facilitate the people working together, that it
14 avoids a world of siloed research and enables a world
15 where we can all learn from and build on each other,
16 which leads to reproducibility.

17 Let's take advantage of modern technology and
18 say that when somebody finds an insight from the All
19 of Us program data, that other people can build on
20 what they've learned, can reproduce that result,
21 extend it a little bit, apply it to new data, change
22 the methods a little bit.

1 So, we wanted a powerful platform to enable
2 collaboration and reproducibility. Given those
3 participant goals and those researcher goals, we took
4 an approach of saying we can now build on modern
5 technology that has been evolving over the last 20
6 years and take advantage of a cloud centric approach
7 to providing data to researchers.

8 Unlike the traditional approach, which always
9 was the only choice of when a researcher wanted to
10 work on a set of data, they would have to download a
11 copy of that data and work on it locally, which works,
12 but unfortunately it means that everyone's working on
13 their own copy in their own silo and it makes it
14 harder to work together -- possible, but it's harder.

15 We said we have an opportunity now to take a
16 cloud centric approach where instead of bringing data
17 to researchers, we will bring the researchers to the
18 data. We will create an environment where researchers
19 can work together on a shared copy of the information,
20 share tools with each other, only collaborate if they
21 want, but now it's easy.

22 Now, when two of us want to collaborate, it's

1 very easy for us to do so because we're working in a
2 collaborative environment. So, that's the approach
3 that we're taking. You'll all get a chance to see and
4 there will be a booth outside afterwards where you can
5 play with the very first taste of that, as Doctor
6 Collins said, we're releasing the tools, the data
7 browser, to look at the aggregate data, and you'll be
8 able to start looking at that.

9 And then we're even more excited about coming
10 up this winter to start giving the first taste of the
11 platform that we've built that will hopefully address
12 those goals in a way that will move research forward.

13 As we do that, we're looking not just at
14 meeting the immediate goals of the program, large as
15 they are, but saying we have an opportunity, we are
16 part of a global community.

17 And I just came from a week of meetings in
18 London, talking to national initiatives from other
19 countries, other organizations, the globe is facing
20 exactly the same needs and opportunities and people
21 are advancing in different ways at different speeds
22 with different insights.

1 We are designing the work we are doing with
2 All of Us to be able to be part of that growing global
3 ecosystem, so that over time it will be possible to
4 build on not just the huge opportunity we have from
5 the communities here who are donating data in America,
6 but to allow cross-analysis, cross-sharing, cross-
7 learning and let other projects benefit from the work
8 we're doing and us to benefit from those.

9 So, we're very excited about the work we're
10 doing, about the first taste of it that we're giving
11 you now, and about the future, thank you.

12 MS. VOLKOW: Happy Birthday All of Us. It's
13 wonderful to be given an opportunity to actually speak
14 to you about why is it this program can be
15 transformative to what we do at the National Institute
16 on Drug Abuse, and I was given 7 minutes by Eric, and
17 I am grateful for that.

18 I said okay, I have to choose one, so then
19 what am I going to choose? Because the opportunities
20 as Francis was saying, this is a resource, and what
21 type of research it will bring about are quite vast
22 and extensive, but I only have 7 minutes.

1 So, of course, what am I going to be speaking
2 about -- the opioid crisis that we're currently living
3 in in our country because its actually responsible for
4 decreasing the life expectancy of Americans, despite
5 the fact that we have an extremely solid healthcare
6 system.

7 So, what is it that drove it? It drove it in
8 a way, lack of knowledge, lack of infrastructure that
9 started with over prescription of opioid medications
10 for patients suffering from pain because we actually
11 did not know how to properly treat that.

12 Now, did we know which patients would be at
13 risk for overdosing, nor do we know yet, who are at
14 risk from dying from addiction.

15 The second, as people became addicted to
16 prescription opioids, we are seeing an increase in
17 deaths from heroin, as more people started to actually
18 find it easier to get access to heroin, as well as
19 individuals initiating the drug use with heroin.

20 And more recently, the mortality has been
21 increased by the emergency of synthetic opioids where
22 patients becoming tolerant to heroin, surpassed only

1 to fentanyl with very high mortality rate. So, what
2 drove this epidemic as I say, it came to two sides.
3 On the one side a tremendous need of patients
4 suffering from pain for the treatment of their
5 condition and on the other one, high vulnerability
6 that we have as some individuals, as some of us, an
7 asked the country to the affects of drugs and to
8 addiction.

9 In the case of pain, we actually recognize
10 that one of the big challenges that we have is that
11 you -- we all have suffer from pain, but just a
12 certain percent go on to transitioning to chronic pain
13 and there are many questions that we don't know about
14 who is at risk.

15 We know that the numbers are actually quite
16 high, that approximately 20% of U.S. Americans are
17 suffering from chronic pain and that comes to an
18 estimated 5 million people.

19 So, if we think of All of Us, where we're
20 going to be collecting 1 million individuals to
21 participate, we will end up by having 200,000 who will
22 have chronic pain. Of those that have in the United

1 States, it is estimated that approximately 8% of them
2 will suffer from high impact chronic pain, and this is
3 pain that interferes with your everyday activities for
4 the past six months.

5 We also know that if we don't treat this, the
6 consequences are devastating. 9% of suicide
7 descendants have evidence of chronic pain. And those,
8 to try to advance our understanding of who's more
9 vulnerable to chronic pain, we have information at the
10 population level -- and the immunology has shown us
11 that women are more vulnerable to develop chronic
12 pain, older adults, unemployed, living in poverty,
13 with public held insurance and world residence.

14 But how does that translate to the
15 individual? So, me, as a doctor, or me, as a patient,
16 know what would be the most sense. I'm a female, but
17 what does that tell me more about my vulnerability?

18 Genetic factors are important and yet we
19 still know very, very little about those genes that
20 make you more vulnerable to getting to that transition
21 from acute chronic pain.

22 And as you get exposed to opioid medications,

1 we know that approximately 10% of individuals would
2 become addicted. But who are they? How do I actually
3 recognize them? From the biological data of course, I
4 have group findings. If you actually have a substance
5 use disorder in yourself or your family, you're at
6 much higher risk of becoming addicted.

7 If you have a of comorbidity psychiatric
8 disease, you are much more likely to become addicted
9 if you are given prescription opioids. But as an
10 individual, how does that translate to me?

11 And being able to understand who's at risk of
12 course, would lead me to maximize and tailor the
13 intervention. And yes, genes are of extraordinary
14 importance in addiction. 50% of the risk of
15 vulnerability for addiction are related to genetics,
16 but we don't understand which ones are they and how do
17 they interact with the environment?

18 And this is exactly why All of Us becomes
19 such an extraordinary opportunity for us in research.
20 I start to -- the main initiative that we are doing at
21 the NIH to address the opioid crisis, we have an
22 initiative called Helping end Addiction Long-term

1 Initiative. It has a component devoted to research
2 that will facilitate, accelerate our development of
3 novel interventions for treating pain and on the other
4 side, opioid use disorder -- accelerate development of
5 interventions that will enable us to treat better
6 patients that become addicted to opioids and to
7 prevent them from overdoses.

8 As part of those projects, we have to dwell
9 into large cohorts and populations. On the pain side,
10 there will be large clinical networks to tell us the
11 efficacy of intervention.

12 And on the side of the opioid use disorder,
13 we're also developing large networks of community
14 programs to delve into the environments and
15 characteristics that make individuals basically on the
16 one hand, vulnerable for pain, vulnerable for
17 addiction, that may actually enable them to predict at
18 one moment which one will be better, which form of
19 this treatment, and which one will respond to the
20 other.

21 To the extent that the All of Us has opened
22 up a window to actually link this program, we will all

1 benefit because it will allow us to bring our findings
2 which up to now, are very important, giving our data
3 and compilations, to actually bring it up to the
4 individual.

5 All of Us matters because it actually
6 addresses disease for which all of us are vulnerable -
7 - will have one vulnerability or the other. And it
8 also matters because it is for each one of us, because
9 it is for each one of us in isolation, and it is for
10 each one of us all together, and it is that all
11 together that will make ultimately the difference to
12 develop better treatments, better preventions for each
13 individual based on their circumstances, thank you
14 very much.

15 MR. GIBBONS: Alright, well good morning.
16 I'm Gary Gibbons, Director of National Heart Lung and
17 Blood Institute. It's my pleasure to also participate
18 in the celebration of the one-year anniversary of the
19 All of Us program.

20 As Francis mentioned, we are privileged --
21 something lost in translation there, okay. We are
22 very privileged in NHLBI that we celebrated the 70
th

1 anniversary of the iconic Framingham Heart Study, one
2 of the early cohorts that Francis alluded to earlier
3 in which that iconic cohort study taught us so much
4 about heart disease in this country.

5 And indeed, it's part of a legacy of our
6 institute in which we've reached out to a variety of
7 populations to develop longitudinal cohort study of
8 which Framingham was the forerunner, and it's been
9 inclusive of the diversity of our country.

10 And indeed, that's one of the things that we
11 think is complimentary about our top med program of
12 program and precision medicine that leveraged our
13 cohorts that include over 150,000 individuals involved
14 in these longitudinal studies which we had deep
15 characterization and at which at this point, we've
16 garnered 150 whole genome part of that population
17 database and includes, indeed, the Framingham study.

18 It compliments I think all of us in the
19 spirit of the participant partnership that is crucial
20 for you to have multiple generations come back yet
21 again and again to contribute their data toward this
22 larger good and social beneficent of participation,

1 but also in including a diverse set of populations.

2 This has created, we think, one of the larger
3 resources in genomics that has been inclusive.

4 Indeed, where the majority of the participants in this
5 genomic resources are those of non-European ancestry,
6 and we believe that this is not something that's just
7 simply politically correct, but indeed it's
8 scientifically driven, only because we understand the
9 diversity of genomic variation across the human family
10 that we'll be able to gain insights into the
11 pathogenesis of disease that affects us all.

12 We were also intrigued by our
13 complementarity. We look forward to how all of us can
14 take things to a larger scale that we could indeed
15 envision in a cohort, say like Framingham, 5,000
16 individuals and it really just stimulates the mind and
17 imagination to think about now a cohort of a million.

18 And so, we're very much excited about who
19 this toddler is going to grow up and become because
20 it's going to enable us to ask questions that -- at
21 scale, in a diverse population that quite frankly were
22 unimaginable previously.

1 It might be able to give us insights into the
2 dynamics of complex traits and disorders in which we
3 know there's a dynamism, and an interactive interplay
4 with our genome and our environment. And just I had
5 to only pick two things to fit into the 5 minutes I
6 had, but I thought I'd start off with one exemplar --
7 Sickle Cell Disease.

8 This is a rare disorder that affects about
9 100,000 African Americans in this country, though it
10 affects every race ethnic group around the world.
11 Indeed, millions around the world are affected by the
12 disease.

13 And as Francis Collins knows, we're dedicated
14 to curing this disorder in a transformative way in the
15 next 5 years. I'm not here to talk about our Cure
16 Sickle Cell Initiative, but indeed, how that variation
17 came about.

18 And it reflected an environmental genomic
19 interaction in which people of African ancestry, our
20 genome has been shaped by that experience of our
21 ancestors and our population history, indeed how we
22 interacted with vectors in that environment that

1 caused malaria and that caused a change in our genome
2 in ways that our body tried to defend ourselves
3 against the complications that probably brought the
4 survival advantage in such that a variant of the
5 defects of the hemoglobin gene actually became
6 advantageous and indeed, became more prevalent in
7 those endemic areas of malaria, resulting in sickle
8 cell traits.

9 And indeed, that has been thought to be a
10 relatively benign condition. So, yes, if you have
11 both copies of that variation, you might have Sickle
12 Cell Disease, a rather devastating illness. But if
13 you had only copy, that might be a good thing,
14 protective against malaria.

15 And indeed, in the comfort of the United
16 States without malaria, it will start to be a benign
17 condition except in sort of rare, extraordinary
18 circumstances.

19 But this is where cohort studies were able to
20 tell us something about this trait which about
21 prevalent in about 5 or 7% of African Americans that
22 might not be quite as benign as we thought. And we

1 are aware of the notion that African Americans have an
2 increased risk of chronic kidney disease, and we're
3 still wondering what are those pre-disposing factors?

4 The cohort studies have taken them all
5 together to try to get up to a little bit of scale to
6 look at this contribution. It started to tell us that
7 perhaps having that sickle cell straight may not have
8 been as benign as we thought and maybe it's a
9 predisposing factor and a contributor to health
10 disparities, we see in chronic kidney disease and may
11 confirm an increased risk.

12 Something about that micro-environment of the
13 kidney that tends to be hypoxic and stressful to cells
14 that might indeed promote damage in this population
15 and explain some of those disparities.

16 It kind of raises the issue of what happens
17 when you do have just one copy of something that might
18 be deleterious, and indeed, understanding what it
19 means to be a Heterozygote or concepts like
20 Haploinsufficiency. What does it mean to have a
21 certain dose of a variation that it might affect the
22 function of a protein?

1 And this is something that we have hundreds
2 of thousands of whole genomes, we're going to have an
3 explosion of trying to understand what each of those
4 variants does, how do they work in a dosage fashion?
5 How do they interact with each other in ways that
6 again, we couldn't imagine consideration years ago?

7 We're starting to appreciate that when it
8 comes to complex traits, much of which will be seen in
9 All of Us cohort, many of which are in our portfolio -
10 - hypertension, high cholesterol, myocardial
11 infarction, coronary disease, asthma, and other
12 disorders -- that these different variants, some of
13 which are influenced by our own population history and
14 ancestry, may be coming together in combination in a
15 way that may identify people at great risk, or might
16 even identify those who are particularly resilient to
17 certain environmental stressors.

18 This is an opportunity now that we have and
19 is starting to emerge. Indeed, a recent study by St.
20 Catherine's to start to look at what are those
21 predisposing factors to heart attack? And use the
22 Framingham risk score -- that classic iconic study

1 that told us how we -- physicians might predict who's
2 at risk.

3 They found, by putting together the genetic
4 variation, he was actually able to identify another
5 high-risk group that Framingham risk score alone would
6 not have picked up, that maybe predisposed to a heart
7 attack. And this is now being tested in a variety of
8 traits such as atrial fibrillation, diabetes, as
9 Francis alluded to earlier, and this represents a
10 whole new window of opportunity for thinking about
11 precision prevention and personalized medicine.

12 These are the capabilities that we believe
13 that the All of Us program will indeed allow us to
14 contemplate so that while we can actually consider
15 with the multiple dimensions, multiple modalities of
16 data collection enabled at scale of one million, we
17 may be able to understand how these variants interact
18 with various environmental influence.

19 We start to envision a day when we know that
20 we can predict that you'll have this irregular
21 heartbeat predisposition called atrial fibrillation.
22 Ordinarily, that might only become manifest when

1 you've come into an emergency room dizzy and short of
2 breath with a rapid heartbeat. What if we already
3 knew by your polygenic risk score your predisposition?
4 What if we already knew that a personal sensor with a
5 watch like this could be detecting your heart rhythm
6 all along?

7 We might even be able to detect the first
8 glimpses of that arrhythmia. Indeed, in ways that we
9 might come in and actually take care of that
10 electrical short-circuit prospectively, proactively.
11 Or, alternatively, even if it happens, we could detect
12 it and using artificial intelligence figure out that
13 that is indeed a worrisome arrhythmia, and in fact
14 press out a message, give you instructions about what
15 you should do to treat it before you even need to go
16 to an emergency room.

17 That's the vision that we have in mind and
18 that's the capability that we think is being created
19 by the All of Us platform. So, we're very excited
20 about the potential for this to transform how we think
21 about precision prevention and personalized medicine
22 the next 5 to 10 years, and that's why we're very

1 excited about your birthday and what we can do
2 collaboratively as part of this partnership with
3 participants to really transform how we fulfill our
4 mission to turn discovery science into the health of
5 the nation affecting all communities. Thank you very
6 much.

7 MR. DISHMAN: Good morning, I'm Eric Dishman,
8 Director of the All of Us research program. Anybody
9 recognize what I'm wearing? Anybody have a Sony
10 Walkman -- the younger people in the crowd?

11 Here it is. Yeah, it's quite a piece of
12 work, the Sony Walkman. I got one when I was 12. I
13 was already starting to train to become a long-
14 distance runner. And it has these things called --
15 I'll show you, for those of you who are younger. This
16 is called a tape.

17 We used to make these things called mix
18 tapes. It was a labor of love, oops, and the problem
19 is as you were doing your mixed tape -- I was going to
20 try to get the tape to spin out here. You know, this
21 would happen -- oh no, right? And then all that work
22 that you had done to build this nice romantic mix tape

1 for your loved one is just gone because the tap got
2 caught in the wheels.

3 Now, you know, that was mobile music. It
4 lasted for 30, 60 or 90 minutes, depending on the
5 length of the tape. When I ran, I had to carry an
6 extra set of batteries and a couple of tapes. If you
7 travelled on a trip, you were carrying a whole piece
8 of luggage with your tape collection with you.

9 And we could not imagine back then like what
10 was going to be possible today, right? I had to put a
11 picture up, because you're going to have to see it
12 back in the audience, right? You think about the
13 Apple ear bud today, right?

14 We could not imagine back then that through
15 voice control you could have any song anywhere for
16 very inexpensively in your pocket today, right? Or in
17 a tiny little wireless thing that fits in your ear.

18 And it's not like, you know, and you think
19 about today really the whole music industry has been
20 transformed, and our relationship with music and our
21 relationship with musicians has been transformed, but
22 this did not happen overnight.

1 It was not from one product. It was not from
2 one company. We often feel like these transformations
3 have just appeared out of the blue and it just
4 suddenly happens, but there is just a lot of
5 continuous innovation going on that finally reached
6 this point where it snowballed into a radical change
7 in the way that we do things, and our relationships
8 with the world around us.

9 That tape is never going to go back in there,
10 even if you try to spin it with a little pencil, which
11 is what you used to do. So, you know, this is kind of
12 an innovation process, right? How do we understand
13 needs? How do we put out early products and
14 prototypes? How do you get community feedback? How
15 do you iterate and improve upon those?

16 This is the process that the All of Us
17 research program, as it celebrates its first birthday,
18 is in and is trying to inculcate in the NIH
19 environment because this process works, repeatedly, as
20 long as you do all the parts.

21 Spend time with people to understand their
22 needs, put out things early and often, even if they're

1 crude or simple. When that came out, everybody said
2 no one will ever use it, your quality of your sound is
3 much better at home with a mounted speaker system that
4 took up your whole living room.

5 No one's ever going to want it, they're toys,
6 they're crude, they're only for the rich because they
7 were really expensive, but over time the innovation
8 process really drove with community feedback,
9 innovations that now really have transformed our
10 relationship.

11 So, here's another example, anybody go to
12 this website back in July of 1995? Right, this is the
13 Amazon original web page, right? You could go online
14 and order a book and it would show up to your house
15 within a week, right?

16 I did this, right? And this is another
17 example where when this came out people sort of, as a
18 joke, nobody's going to do it, why would you want to
19 do this? A bookstore is a much more pleasant place to
20 be. You can just run down to Barnes & Nobles.

21 Remember Borders, right? You used to run
22 down to Borders and go get your book at Borders,

1 right? And it's the same kind of thing where crude,
2 simple, get it out there, get community feedback, make
3 it better and over time you start to transform our
4 relationship to shopping, our relationship to retail,
5 right?

6 And our relationship with each other through
7 these technologies. Sometimes better for the better,
8 sometimes for the worse, and usually both, right?
9 This is the kind of innovation process and the way
10 that it works.

11 So, a year ago today, as Doctor Collins and
12 Doctor Richardson-Heron were standing in Abyssinian
13 Baptist Church in New York City, I was standing in the
14 end zone of Ford Field in Detroit. We had invited
15 community members to come in -- that was one of our
16 seven sites that we launched. There were many people
17 that came into there and said I've never been in here.
18 I've lived in Detroit all my life, but I could never
19 afford a ticket to come to a show here or to go to a
20 sports event.

21 And we were having conversations about
22 precision medicine and engagement and getting involved

1 and trying to sign people up. And I was absolutely
2 terrified. I was in part because I was standing,
3 waiting for the feed from New York to come to Detroit
4 and here's all these people looking at me in the
5 stadium and I'm just shaking and waiting as I do my
6 kind of the part of please let the satellite work.

7 But I was also nervous because we had just
8 finished an alpha and a beta phase of all of our tools
9 to start recruiting participants, and they tested
10 pretty well and we made them better during that, but
11 we're like is this stuff going to work? Is it even
12 going to hold up when everybody clicks on it at the
13 same time?

14 And more importantly, is anybody going to
15 come? And we could not imagine even a year ago, that
16 we'd be standing here today saying oh my gosh, more
17 than 230,000 people have started the process. And
18 we've got this amazing diversity.

19 I mean we had arguments at our consortium,
20 right, saying let's just wait and see who we get, and
21 okay, maybe we'll get 20 to 30% diverse. And we said
22 no, no, no, we're going to try to rethink engagement

1 and the way that you do it with the kind of focus that
2 you are talking about here so that we can come out of
3 the gate focusing on the diversity.

4 Because we do need the science to have to
5 have the diversity of people behind it so that the
6 diversity of cures can exist. So, I was really
7 nervous, and we were just taking our first baby steps.
8 We're still improving these tools.

9 The participant tools have gotten slightly
10 better, we're working on some radical improvements for
11 the participant's portal, all based on community
12 feedback. Put something out, engage, get the
13 feedback, iterate and improve.

14 And I want to thank an amazing number of
15 people who have done this. I want to thank each and
16 every participant. Those of you that joined in the
17 earliest days and those of you still joining now, our
18 tools are pretty crude. We're not yet giving you back
19 information, but we're working on those and testing
20 them and getting them there.

21 And over time the experience is going to get
22 better and better. But every one of you that's come

1 with us since the beginning has been incredibly
2 patient and is really informing the journey that we're
3 going on, our innovation journey as we try to improve
4 this.

5 I also want to thank every single consortium
6 member. We have a consortium of over 2,000 people
7 from scientists to -- and researchers, to social
8 workers, the front line staff and clinics and
9 hospitals who this very day are out recruiting
10 community members that are out engaging, sometimes
11 just creating awareness in their communities of what
12 is research.

13 What is biomedical research? You got to
14 start that kind of conversation before you're trying
15 to get people to sign on the dotted line and say hey,
16 come donate. Come be part of history and within this
17 program.

18 And standing in this building, I want to
19 particularly thank our NIH family. The 27 institution
20 centers have been amazing, from the leaders of those
21 who have given great wisdom to me and to many others.
22 I had to go to Gary and say, "Gary, what exactly is a

1 cohort?" I'm a guy from Silicon Valley, I know
2 innovation process, but what is a cohort, right?

3 And then we have liaisons that Stephanie has
4 been leading with all 27 institutes and centers who
5 participated in that research priorities workshop as
6 we start to try to develop the complex scientific road
7 map for the next decade or more.

8 So, thank you to all of you for getting us to
9 this first birthday. Now today, we're taking our
10 first baby steps on a different innovation journey.
11 This is starting to head down the path of at least
12 making the cohort and the data understandable to the
13 public and to researchers so you can at least start to
14 get the juices flowing in thinking what might I do
15 with that data, as I can start to understand the
16 aggregate statistics and the kind of people who are
17 joining the program.

18 So, we are launching today the beta version
19 of our public data browser. You can go to
20 researchallofus.org. One of our colleagues from
21 Vanderbilt, Regina, will be out in the lobby showing
22 them on kiosk as we get out of this room, but you can

1 go to it right now, researchallofus.org. If it
2 crashes, please don't tell me, it will make me
3 incredibly nervous. I think it's going to work,
4 everything should be fine, but you never know, welcome
5 to the gremlins of technology.

6 And this basically provides summary
7 statistics from our ongoing database, right? So,
8 you'll have the first curated dataset in there which
9 is much smaller in numbers than the total people have
10 joined, because it takes a while to collect that data,
11 clean it, you re-identify it, curate it and make it
12 ready for us all to see.

13 But those numbers will grow over time and
14 you'll be able to see these data snapshots. So, let
15 me just give you a little bit of a sense of it.
16 You'll come to an overview page, up there in that
17 search box you can type any concept that you like. I
18 did the ones that matter to me, kidney, cancer, I did
19 diabetes, I did Alzheimer's, all of these are sort of
20 pervasive in my own family, and sometimes in my body.
21 You can click on the conditions and then you
22 got three kinds of data right now in there, EHR data

1 that we're pulling in, the data from the survey
2 questions that participants are filling out and then
3 some of the physical measurements. And you can just
4 click on those and start to see aggregate statistics.

5 For example, what are the top 10 conditions -
6 - this is based on the EHR data, and you'll see not
7 surprisingly, pain, as Doctor Volkow just talked
8 about, right?

9 As somebody who lived with chronic kidney
10 pain until I got my own genome sequence and got rid of
11 my kidney cancer, I dealt with -- the issue really for
12 me was for 15 years of my 23-year illness, was coping
13 with that chronic pain and trying to decide each day
14 was I going to be basically drunk at work or in pain
15 at work because it was going to be one of those
16 choices as you tried to figure out how to navigate
17 that.

18 And it was a lot of trial and error back then
19 as opening talks, to try to figure out what could they
20 do for this complex individual who is kind of strange
21 and doesn't respond to drugs like we normally see that
22 somebody would do?

1 So, that's the kind of thing that you can go
2 do, and you can start to drill down on that, right?
3 So, we can actually go look at pain and say okay,
4 let's look at the focus in the cohort right now by
5 age, right, and start to look through that.

6 So, you'll be able to play with this and
7 start to look at the demographic details which don't
8 show up very well on the screen. Hopefully, you're
9 already at researchallofus.org and starting to play
10 with it faster than I have.

11 You can go into the survey explorer. So,
12 let's understand the questions that were asked and the
13 kind of answers and how those distribute out by age,
14 right? Do you now smoke cigarettes every day? Some
15 days or not at all, right? And start to get some
16 characterization of what's going on with the people
17 who have participated so far in our efforts.

18 You can also go look at the measurements,
19 alright, so these are the physical measurements that
20 are taken when people come in to give their bio
21 samples. This is the mean blood pressure broken down
22 by male and female systolic as of the current database

1 as we go through there.

2 So, just what we need now is for the
3 community to begin to go with these early simple crude
4 tools and start to get feedback so that we can make
5 those better and better over time. And that is the
6 way that the innovation process works. And the more
7 diverse of the crowd that gives the feedback, the
8 better, right?

9 Large numbers are important, but the
10 diversity of that crowd is really important. We want
11 to hear from participants who are trying to use this,
12 your mom who's trying to use this and give us
13 feedback. It's a pretty challenging tool to use right
14 now, so you have to have a certain amount of visual
15 literacy to be able to go get this, right, but how do
16 we make it even easier for people and we'll be
17 publishing reports for people who this tool proves too
18 difficult to use, so they can still start to
19 understand the basics of it.

20 Now there are some features that we already
21 know that we want to add in. For example, at some
22 point given the amazing diversity that we've achieved

1 so far, we want people to be able to sort by race and
2 ethnicity as well as sexual and gender minorities, and
3 sort of cut that way, but we have not added that at
4 this point.

5 And why is that? It's because we're still
6 engaging with communities to figure out how to do this
7 the right way. One of the innovating things that
8 we're trying to figure out as a program is how do we
9 create an open resource but protect people's identity
10 and data so more and more researchers in the public
11 can access it, but at the same time how do we prevent
12 the kind of awful stigmatizing, unethical research
13 that often gets done with crude analysis of aggregate
14 statistics?

15 So, as we speak, we're having focus groups
16 and interactions with a wide-range of communities
17 around the country to say what's the right balance
18 here. They want to go sort. They said I want to know
19 how many people from my ancestry have actually signed
20 up for the program and what you're finding.

21 We're having conversations with the American
22 Indian and Alaskan native people, right, who have been

1 harmed incredibly by past studies. So, we already
2 know there's going to be new features that we want to
3 add, but we need community input, so go to
4 researchallofus.org, play with this data version and
5 give us feedback.

6 And you can do that by going to support at
7 researchallofus.org and click and just type in the
8 feedback right there. This is a monitored box that we
9 go look through and the feedback can be anything from
10 A to Z, even misspelled something here, this is a
11 weird way that the interface comes up to, here's how
12 you really need to think about packaging the data to
13 really reduce the chance of unethical research that
14 are going to happen as we go through this.

15 So, as I end, and these are different places.
16 And by the way, you can still join. We're not done
17 with joinallofus.org, we've got a long way to go.
18 There has been great progress in this year but if you
19 haven't joined, you can go to joinallofus.org.

20 But what I sort of want you to think about is
21 that innovation process, right? The Walkman may be
22 silly in retrospect, but it was an innovation at the

1 time that started to sound the path. As a guy from
2 Silicon Valley who spent way too much of my life
3 working on the future of entertainment and the future
4 of television, I want to apply these methods to the
5 future of healthcare because we surely need to
6 transform our relationship with the healthcare
7 industry, with healthcare, with health and if we use
8 these methods to engage and understand needs, put
9 early product and prototypes out there, get feedback
10 from the community, incorporate that feedback to
11 iterate and improve, then we will get to the point
12 where we transform not only medicine, but our
13 relationship with health that can be individualized
14 for each and every one of us, thanks for your time.

15 MS. DEVANEY: Thank you, Eric. You are
16 officially on point for making a mix tape for all of
17 us for her birthday. I would like to request "Welcome
18 to the Jungle," as one of the songs.

19 Okay, so we have about 10 minutes left, and
20 we did -- we were intending to save some time for
21 questions and answers. I know we packed a lot into
22 this program today, so we want to hear from you, take

1 some questions. I'll ask anyone from the audience who
2 wants to ask a question to stand up at an aisle mic,
3 and our speakers when they answer, to come to this mic
4 right here in the front.

5 I will also be taking questions from Facebook
6 Live. We have over 1,000 people watching the event
7 live, so thank you for all of you for joining us from
8 where you sit across the country and know that if we
9 don't get to your question today, our team will be
10 answering your questions over the next couple weeks.

11 Okay, so we'll take our first question over
12 here, please introduce yourself and then ask your
13 question.

14 VICK: Hi there, my name is Vick and
15 congratulations on the first year of All of Us. This
16 question is specifically about the Heal Initiative for
17 Doctor Volkow. And just about the level of
18 collaboration that takes place between the Heal
19 Initiative and other institutes, and then how it's
20 leveraging this genetic data to more specifically
21 develop those community-based treatments and
22 interventions.

1 MS. VOLKOW: The Heal Initiative is actually
2 an initiative where most of the NIH centers are
3 participating and that collaboration actually is what
4 makes it so unique because we're bringing expertise
5 across very different domains.

6 As it relates to, I mean, how do we take
7 advantage of the revolution of genetics to help
8 accelerate our discovery? This is again an
9 opportunity that the All of Us is opening the door for
10 all.

11 So, as we're doing clinical trials, basically
12 most of these instances, DNA is being obtained from
13 the participants and are followed-up to try to figure
14 out which are the genes that are going to be able to
15 perhaps predict responses.

16 What's very unique too, about the issue of
17 All of Us that I will bring, which can bring these
18 large project together is with the healing is that it
19 is not just uniquely that it sees that we're going off
20 after pain or addiction because none of us is just
21 pain or addiction, each one of us is an individual in
22 the context of a variety of multiple conditions and

1 environments.

2 So, All of Us, by providing a platform that
3 allows individuals to participate in a larger sample,
4 will enable us to expand the very specifics of the
5 Heal Initiative into a much wider arena.

6 VICK: Cool, thank you.

7 MS. DEVANEY: Thank you, I think we'll take a
8 question from Facebook Live here and I'm going to give
9 this first one to Liz Cohn or Rob Winn, I'll let you
10 guys duke it out.

11 Minorities are least likely to participate in
12 clinical trials. What strategies are being
13 implemented to involve them on the front line? And
14 then the question asker says hopefully nurses. Liz,
15 do you want to address this?

16 MS. COHN: So, thank you for the question and
17 also for the shout out for nurses. So, actually in
18 this -- unlike any other initiative that I've ever
19 been involved with NIH, way back about 3 years ago we
20 started with a community partners workshop, bringing
21 100 people here to the NIH, while just off-site of the
22 NIH campus to really start way back at the beginning

1 before the initiative, as we were beginning to just
2 formulate it to get -- to start to get input, to start
3 to hear people's voices about the opportunities but
4 also the concerns.

5 And that community partners workshop and the
6 continued voice at the table of community partners
7 through genuine, authentic engagement, but also an
8 ambassador's run by Consuelo Wilkins, at Vanderbilt
9 and a number of roundtables that she did has continued
10 to elevate and amplify the voice of communities to
11 this day right now on every single committee that we
12 have through her work and the work of others and mine
13 as well.

14 There's a participant at every one of our
15 steering committee meetings, at every one of the
16 committee meetings, during the initiative and as we
17 move things forward. So, even things like the
18 publications committee, has a representative, a
19 participant representative.

20 I'll speak very briefly about the New York
21 Consortium. Our Participant and Community Advisory
22 Board meets every other week and really is driving

1 some of our work in New York in a really rapid and I
2 think, incredibly engaged fashion. Sometimes, who is
3 leading who depends on the minute, the hour, the day,
4 but I think we have tremendous involvement and that's
5 one of those things that makes this initiative so
6 very, very different from other ones. Do you want to
7 add anything?

8 MS. DEVANEY: Thank you Liz. Okay, another
9 question from Facebook Live, and this one is for
10 Doctor Collins. What diseases will All of Us cover?
11 Many of us have rare diseases, will this program help
12 us?

13 MR. COLLINS: Well again, All of Us aims to
14 try to enroll this incredibly diverse group across the
15 nation, one million folks. It is therefore
16 particularly powerful when you're talking about common
17 diseases because you'll have lots and lots of
18 participants who are affected.

19 I talked about diabetes and Alzheimer's, for
20 a rarer disease it depends on just how rare. If you
21 have something that affects 1 in 2 or 3,000 people,
22 yeah, you're going to have a lot of involved

1 individuals, multiple sclerosis for instance. If it's
2 a really rare disease that maybe affects about 1 in
3 half a million people, then you're not going to have a
4 lot of power in this study and rare disease research
5 is really critical to NIH and it will need support in
6 other ways than this.

7 Let me just say one other thing though. We
8 are going to, because all of these million people
9 eventually are going to have a complete analysis of
10 their DNA sequence, we're going to uncover some
11 surprises where people have a different spelling of a
12 gene that we aren't quite sure what that's supposed to
13 mean.

14 Those will all be pretty rare events, but
15 because people are participants and interested in
16 finding out about themselves, we may learn a lot about
17 rare variants in the human genome, and what their
18 consequences are.

19 So, in that regard this will be a big
20 contributor to rare disease research.

21 FEMALE SPEAKER: Okay, so this question is
22 limited to the interim intramural program, and you

1 know, in line with this rare disease theme. So, we
2 have an excellent program for rare disease. Can the
3 interim intramural investigators sort of partner with
4 the All of Us study for sort of a follow-up of their
5 rare disease cohorts?

6 So, for example, you know we have a rare
7 disease of a family over in insufficiency and
8 internally we had seen more than 500 patients here at
9 NIH. Now, the resources are not there to sort of
10 bring all of them back here for follow-up, but if we
11 could use this mechanism in the community, patients
12 can go and then intramural researchers can also, sort
13 of, you know, get access to the data for those
14 patients.

15 So, I'm thinking about this intramural
16 extramural collaboration.

17 MS. DEVANEY: Yep, Eric.

18 MR. DISHMAN: So, it's a great question. I
19 think the way I often talk about it when I'm out
20 talking to folks at institutes and centers, both
21 intramurally and extramurally is, there's kind of
22 three buckets to think about collaboration with this.

1 And one thing I keep telling everybody is
2 like, we're not quite ready yet, right? Because we're
3 just trying to get the basics up and running. But one
4 is just leveraging the resource as it is and it's
5 intentionally designed not to be a cohort or cohorts,
6 but at the same time there's another model that we're
7 exploring that I sometimes call the franchised model
8 that says, hey, if you want to run 4,000 people with
9 this rare disease on our same platform, so that it's
10 completely comparable to the million.

11 And, you know, you've got the funding to do
12 that, we could set things up to where we could go do
13 that. A third is just to actually then propose -- I
14 want to do an ancillary study where I'm going to
15 collect a whole lot more data than you did, and
16 actually be able to bring it in there.

17 There's many, sort of rare disease
18 foundations externally that have come to us saying we
19 know that you don't want to get 20,000 people with
20 this incredibly rare disease, and the million, but can
21 you be a million twenty thousand and partner with us
22 to do that?

1 So, we're starting to try to think through
2 what we would need technically and policy-wise and
3 just practically to do all those things and I think
4 we'll get there. I don't think we're quite there as
5 we learn how to walk and start to talk, but I think
6 that's definitely the vision of what we're trying to
7 get to.

8 MS. DEVANEY: Thank you, and I think we'll
9 take one more question.

10 MR. ANDREWS: Cliff Andrews from Johns
11 Hopkins and the Harvard Personal Genome Project. I
12 think we're all very pleasantly surprised by the
13 numbers after one year. What's the long-term picture
14 you're aiming for a million, could you go beyond that
15 and is it 10 years that you're planning to study?

16 MR. DISHMAN: So, I got to tell you one of
17 the reasons I, you know, left Silicon Valley to take
18 this job was I was like if we bring the right
19 processes here and get good at them, I believe we can
20 blow way past a million.

21 I'm not committing to it yet, we think right
22 now at current course and speed it will take about

1 five and half, 2022-2023 we have different models.
2 Well, one of the great things we don't know is we've
3 done a great job of bringing people in with that
4 diversity, but can we sustain it, right?

5 And how many more people are we going to have
6 to over-recruit because a lot of people may drop out
7 or may lose interest. In our first strategic
8 objective as a program is to nurture relationships
9 with a million or more people from all walks of life
10 for a decade.

11 You know, one year in we can't tell if we're
12 really nurturing really well. We've clearly done
13 something different to get people in initially,
14 because the numbers wouldn't be this high otherwise,
15 but I think that's one of the things we have to figure
16 out.

17 I think if you fast forward two or three
18 years and we start to say hey, we've gotten really
19 good at some of these processes, we're really
20 confident, our analytic skills are really good. We
21 know how to pop in to a part of the country where we
22 have no presence and pull up clinicians and others to

1 be able to do the blood draws and the samples, and we
2 really know how to sustain those people, I think
3 that'd be great.

4 Right now, we don't have a lot for you as
5 participants in there. We're trying to add some
6 return of information, you know, late this year and
7 even more into next year. So, there's not a huge
8 value proposition for those who have joined yet, and I
9 know that, and we admit that, but it also takes time
10 to do that right.

11 So, I think we'll blow way past a million,
12 but right now I'm trying to say let's stay focused on
13 job one and then once we get good at it, we'll start
14 surprising people when we move well beyond that.

15 MR. ANDREWS: Is it 10 years or longer?

16 MR. DISHMAN: Well, we think 5 to 6 years to
17 get to a million, and a sustained million who have
18 completed, you know, the continuous protocol as we go
19 through there, but then the follow-up right, we're
20 working now on what's going to be the follow-up. How
21 much of the current protocol will we repeat?

22 If we ask people to come in and do additional

1 bio specimens, what additional bio specimens would we
2 capture? People certainly talked to us about imaging.
3 Just every time somebody comes to us with a proposal,
4 I always say just remember, it's times a million.

5 Those people come to us like -- "This only
6 costs 5,000 per person to run this thing." And it's
7 like times a million, times a million, times a
8 million, so sometimes we're waiting for technologies
9 to scale to a cost where we can afford to do it for
10 all million people as well, alright.

11 MS. DEVANEY: And with that, I want to thank
12 you all for coming here in person today and for
13 everyone who tuned in live to watch us on Facebook and
14 the NIH video cast. I want to thank our speakers for
15 making this symposium so rich with information and so
16 fun.

17 And I want to take a moment to acknowledge
18 the teams that are working so hard day in and day out
19 on this program from across the country. We truly
20 have one of the most passionate and dedicated set of
21 folks working on this program from institutions from
22 east to west coast and the team here at NIH who has

1 been working with so much dedication and passion for
2 the past two years, and keeping it going. I want to
3 also take a moment to acknowledge that when this
4 program first came to be, there was no office, there
5 was no staff, and we relied on a lot of help from
6 folks at the institutes and centers and people just
7 really dug in, even those who had full day jobs and
8 became a really important set of contributors to what
9 our program is today.

10 So, as you leave today, I want to take a
11 moment to acknowledge all of those people and please
12 take a moment to appreciate the names on the screen,
13 thank you everyone.

14 (Whereupon, at 11:30 a.m. the meeting of NIH
15 was concluded.)

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